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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,430	08/18/1999	PAUL A. MOORE	PF466P1	6501

22195 7590 11/19/2002

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	31

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/376,430	Applicant(s) MOORE ET AL.	
	Examiner Eileen B. O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24-39* is/are allowed.

6)☒ Claim(s) *40-46 and 48-104* is/are rejected.

7)☒ Claim(s) *47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 24-104 are pending in the instant application. Claims 40, 50, 51,64, 76, 100-102 have been amended and claims 103 and 104 have been added as requested by Applicant in Paper Number 30, filed Sept. 9, 2002.

Withdrawn Rejections

2. The rejection of claims under 35 USC 101 is withdrawn in view of Applicants' amendment.

Maintained Rejections

Claim Rejections - 35 USC § 112

~~The following is a quotation of the first paragraph of~~ 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.1 Claims 40-42, 44-46, 50-79, 81-83 and 85-104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO: 2 and for polypeptides consisting of fragments of SEQ ID NO: 2, does not reasonably provide enablement for polypeptides comprising only portions of SEQ ID NO: 2 or for polypeptides having homology to the polypeptide of SEQ ID NO: 2, for reasons of record in the previous Office Action, Paper No. 26, at page 6, and below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant application teaches that the CRCGCL polypeptide is expressed only in activated T-cells, which is confirmed in the Rule 132 Declaration of Dr. Paul Moore submitted with the present amendment; therefore the polypeptide is enabled for use as an activated T-cell marker. However, claims 40-42, 44-46, 50-79, 81-83 and 85-104 encompass a virtually limitless number of polypeptide variants of SEQ ID NO: 2, and the specification has failed to teach how to use other claimed polypeptides that could not be used as an activated T-cell marker.

The rejection under 35 U.S.C. 101 has been withdrawn, because Applicants have demonstrated that the CRCGCL functions as a cytokine, binding a cytokine and stimulating a Jak-STAT signal transduction pathway, however, the claimed variants to the polypeptide of SEQ ID NO: 2 are not enabled for use. The specification discloses that CRCGL shares homology with members of the cytokine receptor family, and that binding of a cytokine to members of this family stimulates certain and often independent signal transduction pathways, and also that cytokines that bind to members of this family are important for the growth and differentiation of immune cells, such as T and B lymphocytes, natural killer cells, macrophages and monocytes, and that these cytokines have overlapping biological effects that in part result from the use of the shared receptor subunit gamma c (see pages 1-2). The specification also provides guidance to one skilled in the art to try various experiments through which the activity (if any) of CRCGCL on specific cell types might then be determined (e.g. see Examples 14-17, pages 150-156). These suggested experiments, however, provide the skilled artisan with only a starting point for further research and investigation. The specification has failed to teach one of skill in the art which cell types to use, if any can be used, to regulate cell differentiation and/or proliferation with CRCGCL. Furthermore, if certain cell types can be regulated with the claimed invention,

then the specification has not provided guidance as to the nature of the regulation, e.g. the specification has not taught whether to use CRCGCL to promote or inhibit cell differentiation and/or proliferation. The specification puts forth that the closest homologue of CRCGCL is the Interleukin-2 receptor gamma. Applicants submit an executed Rule 132 Declaration by Dr. Thi-Sau Migone, in which she contends that after reading the specification, she understood that the CRCGCL receptor protein is only expressed in activated T-cells, that the CRCGCL receptor protein possess a Jak box and was found to interact with a Jak kinase, that the specification asserts that the CRCGCL receptor protein can be used to diagnose or treat immune and autoimmune disorders, specifically, for example, that antagonists to CRCGCL receptor protein can be used to inhibit the proliferation of T-cells (paragraphs 14, 15 and 17 of Dr. Migone's Rule 132 Declaration), and that this understanding was based upon the teachings of the specification as well as what was known in the field of cytokine research at the time the application was filed.

Dr. Migone's Declaration and Applicant's arguments as to the activity of the proliferative/differention activities of the CRCGCL receptor protein has been fully considered but not deemed persuasive. At pages 96-113 the specification simply makes generalized statements regarding any potential activity of the polypeptides toward any number of immune cell types and an extensive list of diseases or disorders that the CRCGCL receptor may be involved in, and which could be used therapeutically or diagnostically. Statements such as "CRCGCL polynucleotides or polypeptides, or agonists or antagonists of CRCGCL, can be used to differentiate, proliferate, and attract cells, leading to the regeneration of tissues", page 111, line 31-33, for example, do not provide the artisan with any particular knowledge – only that the polypeptide might be tested for such activities. The specification does not provide any working

examples of any proliferative or inhibitory effects of the CRCGCL polypeptide on any cell type, and the prior art fails to provide adequate guidance as to what cell types could be regulated by the CRCGCL polypeptide.

Thus, due to the large quantity of experimentation necessary to determine which cell types could be used with the claimed invention and then to determine the nature of the regulation of the cells that are to be used, the absence of working examples wherein CRCGCL is used to regulate cell proliferation and/or differentiation, the complex nature of the art in which it is taught that cytokines have overlapping biological effects that in part result from the use of the shared receptor subunits, undue experimentation would be required of the skilled artisan to use the claimed invention commensurate in scope with the claims.

3.2 Claims 40-42, 44-46, 50-79, 81-83 and 85-104 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Action, Paper No. 26, at pages 6-8, and below.

Applicants traverse the rejection and argue that the test for the written description requirement is whether one of ordinary skill in the art could reasonably conclude that the inventor had possession of the claimed invention in the specification as filed, and site *Vas-Cath Inc. v. Mahurkar*, *Union Oil Co. v. Atlantic Richfield Co.*, and *In re Wertheim*. Applicants argue that the instant specification clearly teaches N- and C-terminal deletion mutants, variants exhibiting certain % identity, preferred fragments and that the specification further teaches that most of these mutations can be made without affecting the biological activity of the protein.

Applicants' arguments have been fully considered but are not deemed persuasive. The skilled artisan readily appreciates that the claims encompass a genus, that for any practical purpose, contains an essentially limitless number of variants. The disclosure of a single polypeptide sequence, which does not have the enabled uses as recited in the claims, is not sufficient to describe this practically limitless genus. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 43, 48, 49, 80 and 84 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4.1 Claims 43, 48 and 49 recite the limitation "amino acid sequence (c)", and there is no antecedent basis for this limitation in the claims.

4.2 Claims 80 and 84 recite the limitation "amino acid sequence (d)", and there is no antecedent basis for this limitation in the claims.

Conclusion

5.1 Claims 24-39 are allowed.

5.2 Claims 40-46 and 48-104 are rejected.

5.3 Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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